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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,815	02/19/2004	Xiang Yang Zheng	LIFE-043DIV	7071

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/783,815	Applicant(s) ZHENG ET AL.	
	Examiner Maureen M. Wallenhorst	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-69 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63 and 64 is/are allowed.
- 6) ☒ Claim(s) 55, 56, 58, 65 and 67-69 is/are rejected.
- 7) ☒ Claim(s) 57, 59-62, 66 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/19/04 & 5/10/04</u> . | 6) <input type="checkbox"/> Other: ____. |

1. The disclosure is objected to because of the following informalities: On page 1 of the specification in the first sentence (“Cross Reference to Related Applications”), the following phrase should be inserted after the phrase “Serial no. 10/055,788, filed on January 16, 2002,”: -- now US Patent no. 6,746,872, issued on June 8, 2004—so as to update the status of the parent case.

Appropriate correction is required.

2. Claims 65 and 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 3 of claim 65, the phrase “said frangible beads” lacks antecedent basis since claim 65 depends from claim 58, and claim 68 does not positively recite frangible beads.

On line 4 of claim 67, the phrase “said plasma” lacks antecedent basis since claim 67 depends from claim 63, and claim 63 does not positively recite plasma in the coagulation test evaluation system. See this same problem on line 3 of claim 68 since claim 68 depends from both claims 66 and 67.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 55-56, 58 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanz (US Patent no. 3,692,487, submitted in the Information Disclosure Statement filed on February 19, 2004) in view of Bull (US Patent no. 5,275,953).

Sanz teaches of a container for performing coagulation tests on samples of plasma. The container comprises a first enclosure or compartment E1 containing a suspension of at least one blood coagulation factor that serves to initiate blood clotting, and a second enclosure or compartment E2 containing a solution of a calcium salt. The two compartments are connected to one another through a frangible membrane. When performing a blood coagulation test, a plasma sample is placed into the first compartment of the container to mix with the blood coagulation factor, and then the frangible membrane is ruptured so as to combine the plasma and blood coagulation factor with the solution of calcium in the second compartment to initiate the

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coagulation process. Sanz teaches that the blood coagulation factor in the first compartment is preferably thromboplastin, but can be anything that initiates the clotting cascade. See Figure 1, lines 43-75 in column 4 and lines 1-26 in column 5 of Sanz. Sanz fails to teach that the blood coagulation factor in the first compartment can be plasma aggregatable particles.

Bull teaches of a container for collecting a blood sample. In the embodiment depicted in Figure 8 of Bull, a blood extracting and receiving assembly 42 is taught that includes a blood receiving chamber 12 and an auxiliary chamber 44 having a frangible diaphragm 46 extending across the chamber 44 for separating the chamber 44 from the chamber 12. The chamber 44 holds plasma aggregatable particles 48 such as ground glass or diatomaceous earth that are introduced into the chamber 12 holding a collected sample of blood by urging auxiliary plunger 50 toward diaphragm 46 to push the clotting substance 48 into the chamber 12. See lines 48-68 in column 8 and Figure 8 of Bull. The clotting substance 48 serves to initiate blood clotting by reacting with plasma and causing the particles to aggregate.

Based upon the combination of Sanz and Bull, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use plasma aggregating particles as the blood coagulation factor in the first compartment of the container taught by Sanz since Sanz teaches that the blood coagulation factor can be any substance that serves to initiate the enzymatic reactions of the coagulation cascade, and Bull teaches that plasma aggregatable particles can be inserted into a container through a frangible membrane to initiate blood clotting by reacting with plasma and starting the coagulation cascade.

7. Claims 57, 59-62 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the

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base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a container having three compartments therein separated by frangible barriers, with one compartment holding plasma aggregatable particles, one compartment holding a solution of calcium and one compartment holding a citrated plasma sample. In addition, none of the prior art of record teaches or fairly suggests a coagulation test evaluation system comprising at least one frangible bead containing plasma aggregatable particles, at least one frangible bead containing a solution of calcium ions and a container for holding the frangible beads.

8. Claims 63-64 are allowable as is over the prior art of record for the same reasons as given above.

9. Claims 67-69 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of Grippi who teaches of a blood collection assembly containing a frangible receptacle therein; and Zheng et al, which corresponds to the parent application of this instant application.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 16, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1700